

§ 158.2082

40 CFR Ch. I (7–1–11 Edition)

1. Data must be provided in accordance with § 158.320.

2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.

3. Data must be provided in accordance with § 158.325, § 158.330, and § 158.335.

4. Data must be provided in accordance with § 158.340.

5. Data must be provided in accordance with § 158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAI) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit.

6. Data must be provided in accordance with § 158.350.

7. Data must be provided in accordance with § 158.355.

8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.

9. Required if the product contains combustible liquids.

10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

11. Required if the test substance is soluble or dispersible in water.

12. Required if the product is a liquid.

13. Required when the technical chemical is a solid at room temperature.

14. Required when the technical chemical is a liquid at room temperature.

15. Required for water insoluble test substances (>10-g/l) and fibrous test substances with diameter $\geq 0.1 \mu\text{m}$.

16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.

17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.

18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.

19. Not required for salts.

§ 158.2082 Experimental use permit biochemical pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a par-

ticular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, *i.e.*, naturally occurring insect repellents and attractants, semiochemicals (e.g., insect pheromones), natural and plant growth regulators. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use. Data are also conditionally required for aquatic nonfood use if there is direct application to water that could subsequently result in exposure to food.

(2) Data are conditionally required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses would be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing end-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern. All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Data table.* The following table shows the data requirements for biochemical pesticides residue. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns				Test Substance	Test Notes
		Terrestrial	Aquatic	Green-house Food	Indoor Food		
		Food/Feed	Food				
Supporting Information							
860.1100	Chemical identity	CR	CR	CR	CR	TGAI	1, 2, 4
860.1200	Directions for use	CR	CR	CR	CR	--	1, 3, 4
Nature of Residue							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	TGAI	1, 4, 5, 6
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	TGAI or plant metabolite	1, 7, 8, 9, 13
Magnitude of the Residue							
860.1400	Potable water	NR	CR	NR	NR	TGAI	1, 11
860.1400	Fish	NR	CR	NR	NR	TGAI	1, 12
860.1400	Irrigated crops	NR	CR	NR	NR	TGAI	1, 13
860.1460	Food handling	NR	NR	NR	CR	TGAI	1, 14
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or plant metabolites	1, 7, 8, 9
860.1500	Crop field trials	CR	CR	CR	CR	TEP	1, 3, 4
860.1520	Processed food/feed	CR	CR	CR	CR	TEP	1, 15
860.1540	Anticipated residues	CR	CR	CR	CR	Residue of concern	1, 9, 16
860.1550	Proposed tolerances	CR	CR	CR	CR	--	1, 17
860.1560	Reasonable grounds in support of the petition	CR	CR	CR	CR	--	1, 9
860.1650	Submittal of analytical reference standards	CR	CR	CR	CR	TGAI and residue of concern	9, 18

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced referenced in the last column of the table contained in paragraph (d) of this section.

1. Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical agents in the biochemical human health assessment data requirements, § 158.2050.

2. The same chemical identity data are required for biochemical product chemistry data requirements, § 158.2030 with an emphasis on impurities.

3. Required information includes crops to be treated, rate of application, number and

timing of applications, preharvest intervals, and relevant restrictions.

4. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions.

5. Required unless it is an arthropod pheromone applied at a rate less than or equal to 150 grams active ingredient per acre.

6. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

7. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from

the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

8. Livestock feeding studies are required whenever a pesticide residue is present in livestock feed or when direct application to livestock uses occurs.

9. Required if indoor use could result in pesticide residues in or on food or feed.

10. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

11. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

12. Data on fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

13. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

14. Data are required whenever a pesticide may be used in food/feed handling establishments.

15. Data on the nature and level of residue in processed food/feed are required when detectable residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16. Anticipated residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level of exposure. Data, using single serving samples of a raw agricultural commodity, on the level or residue in food as consumed would be used to obtain a more precise estimate of potential dietary exposure. These data may also include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

17. The proposed tolerance must reflect the maximum residue likely to occur in crops, in meat, milk, poultry, or eggs.

18. Required when a residue analytical method is required.

§ 158.2083 Experimental use permit biochemical pesticides human health assessment data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the human health assessment data requirements for a particular biochemical pesticide product.

(2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.

(b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	

Tier I